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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,858	12/05/2001	David C. Yeomans	582.02	8925

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,858

Applicant(s)

YEOMANS, DAVID C.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on May 13, 2004 has been entered. Claims 1-13 are pending. Any rejection that is not addressed in this Office Action is obviated in view of the Amendment.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Iadarola et al WO 02/076444 A1 ("Iadarola").

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant argues that Iadarola fails to teach the instantly claimed kits with an amount sufficient to relieve discogenic pain. (see arguments at page 5). Contrary to Applicant's assertion, the doses disclosed by Iadarola ranges from about 50 nanograms to about 50 micrograms which is within the instantly claimed amounts. (see page 23, claim 9). Moreover, the kits of Iadarola provide instructions how to use the kits. (see page 16, 20 and 25). Therefore, all elements of the instant claims are described.

Claim Rejections - 35 USC § 103

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iadarola in view of Yuzuru Takashai et al ("Takashai") (Neuroscience Letters, 161, 1-3 (1999), IDS, Paper no. 6) and Brown US patent 4,696,816.

The instant claims are directed to administration of vanilloid 1 receptor agonist intradiscally. The scope of the claims is not specific to any particular type

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of patients, therefore, a showing of intradiscal administration of a vanilloid 1 receptor meets the limitation of the instant claims.

The teachings of Iadorola are described above. Iadorola teaches the use of VR1 agonists to ablate C-fiber neuron. (page 5, lines 13-15; page 11, lines 16-19). Iodorola teaches that his methods can be used in treating pain effecting spinal column. (page 4, line 30-31). Such teaching encompasses the term "discogenic." Iodorola further teaches his methods to be practiced in human or other mammals (page 16, lines 8-10). Iodorola meets all the limitations of the instant claims, except he does not explicitly teach intradiscal administration of a VR1 agonist.

Takashai teaches direct administration of a VR1 agonist such as capsaicin, a C-fiber stimulant, into rats' annulus fibrosus of disc using a microsyringe for pain that are caused by lesions in spinal disc. (see page 1, 2nd and 4th para; page 2, 2nd para). Takashai further suggests the presence of sensory C-fibers that innervates the intervertebral discs and its potential role in treating pain associated with disc lesions (see abstract, page 3, last para).

Brown is used to show that intradiscal administration of suitable pharmaceutical agents is effective for discogenic pain resulted from disc displacement. (see abstract, col 3, line 30-col 4, line 68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Iadorola's methodology, and instead of intrathecally administering his VR1 agonist, employ the intradiscal administration

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technique taught by Takashai and Brown to treat discogenic pains of spinal column.

The ordinary skill in the art would have been motivated to do such modification, because as taught by Takashai, such lesions within the spinal discs are innervated by C-fibers and one of ordinary skill in the art, as taught by Brown, would have had a reasonable expectation of success in providing the pharmacological effects when administering suitable agents intradiscally.

Claim Objections

Claims 1, 3-6, 8-9 are objected to because of the following informalities: the recitation of the instant methods is ambiguous, as it does not appear to contain an active step. Specifically, it fails to address who is the recipient of the instant method. Examiner suggests clarification of the claim 1 by inserting a recitation of "comprising intradiscal administration of vanilloid receptor 1 agonist to patients in need thereof..."

Response to Arguments

Applicant's arguments filed May 13, 2004 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, all elements of the claims are described in the

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combined teachings of Iadorola and Takahashi. The shortcomings of Iadorolla reference; therefore, is not a reason of nonobviousness.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the cited references are within the same field of endeavor, specifically teach all elements of the instant claims, and predict reasonable expectation of success upon intradiscal administration of a suitable agent such as capsaicin. Therefore, their combined teachings are not a case of improper hindsight, rather, *prima facie* obviousness.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action because it modified the scope of the claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is


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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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